HAMILTON QUALITY LLC

U.S. Quality Intelligence Brief

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This week's developments put the supporting evidence behind quality decisions under scrutiny: the integrity of laboratory results, the justification for retesting, the escalation of contamination signals, and the controls supporting product potency. Device alerts and blood-safety communications add a related question: can the controls in place reliably detect or prevent the risk being assessed?

Reading note: Warning-letters reviewed were publicly posted on November, 3, 2026. Publication dates may differ substantially from issuance and inspection dates, as the agency usually gives companies time to respond to initial form 483 findings and Warning-letters. Subsequent correspondence or corrective actions may change the regulatory status of the matters described. Findings below are attributed to FDA's published records; "Why It Matters" and "Carry Forward" provide Hamilton Quality's analysis, not additional FDA findings.

1. Pritam International: FDA Finds an "Isolated Act" Explanation Inadequate

In its October 27 warning letter, the FDA described microbiological plates with visible growth during an inspection of Pritam International's Indian facility. The following day, plates labeled as the same samples showed no visible growth. Investigators also identified discrepancies in handwritten sample identification.

According to the letter, the firm attributed the plate substitution to a deliberate but isolated act by a microbiologist. It reported retraining, tamper-evident seals, color coding, and concurrent plate reading by two analysts. FDA found the response inadequate, stating that it did not sufficiently address broader weaknesses in quality-unit oversight, data integrity, and quality culture. The agency requested independent assessments, a comprehensive investigation, retrospective product-risk evaluation, stronger sample custody controls, and sustained CAPA oversight. FDA

FDA also cited inadequate controls for components at risk of diethylene glycol or ethylene glycol contamination. The letter records a September 10 voluntary recall of all unexpired toothpaste drug products shipped to the United States between September 2024 and

August 2026, and placement of the firm's drugs on Import Alert 66-40 on September 3. These were earlier actions described in the newly published letter.

Source: FDA Warning Letter — Pritam International Private Limited

Why It Matters

Identifying an individual act does not, by itself, explain why the quality system permitted it or establish the extent of its consequences. When sample identity or original results become unreliable, the investigation should address both the immediate event and the historical decisions that may have depended on similarly vulnerable controls.

Carry Forward

Trace the sample from collection through final reporting. Identify the evidence that establishes its identity, custody, original observations, and review. Then assess whether those controls were sufficiently reliable during the period covered by the retrospective investigation.

2. Next Medical: Passing Retests Did Not Resolve Failed Environmental Results

FDA posted its August 19 warning letter to Next Medical Products Company on November 3. The letter describes environmental results of 4,100 and 4,000 colony-forming units, followed by passing retests without a documented justification for dismissing the original results or an out-of-specification investigation. FDA also cited a subsequent result of at least 25,000 CFU without initiation of corrective and preventive actions. FDA

The agency connected these findings to contaminated ultrasound-gel complaints and inadequate CAPA procedures. It rejected a proposed approach that would trigger environmental testing only after finished-product microbial failure. FDA also cited deficiencies in preservative and labeling change controls, an unsubmitted correction-or-removal report, and a formulation change it determined required a new 510(k). The letter records the firm's disagreement with aspects of FDA's labeling assessment; FDA found its response inadequate. FDA

The November–December 2025 inspection occurred under the former Quality System Regulation. FDA stated that proposed or implemented corrective actions must meet the Quality Management System Regulation requirements effective February 2, 2026.

Source: FDA Warning Letter — Next Medical Products Company, LLC

Why It Matters

A passing retest adds information; it does not explain the original failure. An investigation needs a scientifically supported basis for determining what each result means and whether invalidation is justified.

Environmental monitoring, complaints, finished-product testing, and design changes should also inform a common assessment of process and product risk. Reviewing each in isolation can obscure a developing contamination problem.

Carry Forward

Review retest rules and CAPA escalation criteria together. Confirm that adverse environmental findings receive a documented assessment even when finished-product results pass, and that proposed remediation meets the regulation currently in effect.

3. FDA Finalizes Lifecycle Recommendations for CGT Potency Assurance

On November 2, FDA announced final guidance, *Potency Assurance for Cellular and Gene Therapy Products*, replacing its 2011 potency-testing guidance. The document describes an integrated approach spanning process design, materials, process parameters, in-process controls, release testing, and continued verification. Its recommendations are nonbinding except where existing statutory or regulatory requirements apply.

The FDA News Release

FDA recommends phase-appropriate release testing tied to potency-related critical quality attributes. For most CGT products, this should include at least one bioassay measuring biological activity related to the intended therapeutic effect. For licensed products, the guidance states that potency-release samples must be collected after manufacturing steps that may affect potency.

For products whose extremely short shelf lives prevent completion of a bioassay before release, FDA discusses physicochemical release assays and risk-based use of bioassays evaluated after release. It also recommends strengthening other controls when one part of the strategy cannot adequately mitigate potency risk.

Source: FDA Final Guidance — Potency Assurance for Cellular and Gene Therapy Products

Why It Matters

Potency assurance depends on the combined performance of manufacturing controls and analytical methods. A passing release result is most informative when the organization understands what the assay measures, what it may miss, and how the remaining controls address those limitations.

Carry Forward

Map potency-related attributes to material controls, process parameters, in-process tests, release assays, and stability monitoring. Identify any risk that depends heavily on a single control, then assess the evidence supporting that control's capability and reliability.

4. Platelet-Sepsis Communication Emphasizes Event-Specific Investigation

In a November 5 safety communication, FDA reminded blood establishments and transfusion services that septic reactions can occur despite pathogen reduction or bacterial testing.

Since May 2025, FDA had received reports of septic reactions that included two fatalities following transfusion of pathogen-reduced platelets and two following platelets prepared using other bacterial-mitigation strategies. These reports should not be read as establishing a common cause across the events.

FDA emphasized thorough, documented investigation of suspected septic transfusion reactions and cautioned against assuming that a new event shares the cause of earlier cases. It advised considering retention of implicated bacterial isolates, reiterated prompt reporting to blood suppliers, and identified applicable fatality-notification and device-reporting obligations.

Source: FDA Safety Communication — Septic Transfusion Reactions from Bacterial Contamination of Platelets

Why It Matters

A validated mitigation process does not eliminate every residual risk. Likewise, a familiar event pattern does not establish a familiar root cause. Prior investigations can inform hypotheses, but the current investigation still needs evidence that supports its own conclusions.

Carry Forward

Preserve the material and records needed to evaluate competing explanations. Use prior cases to guide the investigation without allowing an earlier conclusion to determine the outcome in advance.

5. Records Requests Carry Substantive Compliance Consequences

Recent warning letters illustrate distinct consequences of inadequate records, inconsistent records, and failure to provide requested information.

Guangdong Bangze Medicine. Following review of records supplied under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act, FDA cited inadequate component testing, insufficient demonstration of supplier-certificate reliability, finished-product testing deficiencies, and weaknesses in stability, process controls, and quality-unit oversight. FDA recommended a qualified consultant and a comprehensive six-system audit.

Source: FDA Warning Letter — Guangdong Bangze Medicine Co., Ltd.

Guangzhou Jiugong. FDA identified conflicting color-additive information across product labeling, formulation records, and a certificate of analysis. The label identified a color corresponding to the delisted FD&C Red No. 2. FDA requested distribution and customer information, a formulation-wide risk assessment, and a plan addressing distributed-product risk. The discrepancies concern what the documents represented; they do not establish that all three listed color additives were present in the product.

Source: FDA Warning Letter — Guangzhou Jiugong Research and Development Biotechnology Co., Ltd.

Guangdong Bisutang. FDA stated that the firm did not supply requested records despite repeated outreach, including a delivered written request. The agency reported placing the firm's drugs on Import Alert 66-79 and stated that it lacked information establishing the facility's level of quality assurance. This records-access issue differs from deficiencies identified through examination of submitted manufacturing or laboratory records.

Source: FDA Warning Letter — Guangdong Bisutang Biotechnology Co., Ltd.

Why It Matters

A records request warrants the same disciplined preparation as an inspection. Documents must be complete, internally consistent, and supported by underlying evidence. Unresolved contradictions can undermine confidence in both the submission and the quality decisions it describes.

Carry Forward

Assign ownership and deadlines for regulatory requests. Before submission, reconcile formulas, labels, specifications, certificates of analysis, batch records, and distribution information. Explain and resolve discrepancies through controlled processes while preserving original records.

6. Device Alerts Highlight Assembly Controls and Field-Action Scope

B. Braun Streamline Bloodline Sets

FDA's alert covers three lots of Streamline Bloodline Sets for Dialog+. According to the alert, B. Braun reported omission of a required solvent-application step during assembly, resulting in inadequate dialyzer-connector bonding. Detachment or leakage could cause blood loss, treatment interruption, clotting, or air entry into the blood circuit. The alert directs users to cease use and quarantine affected products. B. Braun reported no associated serious injuries or deaths as of October 10.

Source: FDA Early Alert — B. Braun Streamline Bloodline Set for Dialog+

ButterflyBVM Resuscitators

FDA's alert describes the potential for holes to develop in the bellows of certain ButterflyBVM resuscitators, causing leakage and inadequate ventilation. Lots 000109–000117 are subject to removal, with replacement devices to be available first. Specified earlier lots are subject to updated instructions, including testing before every use and availability of backup devices. Compact Medical reported no associated serious injuries or deaths as of November 2. Consult the alert for complete lot identification and instructions.

Source: FDA Early Alert — ButterflyBVM Removal and Updated Use Instructions

Why It Matters

An omitted assembly step raises questions about both prevention and detection: what confirms that the step occurred, and what verifies the resulting bond?

A field action that distinguishes between removal and continued use under revised instructions raises a separate evidence question: what supports the lot boundary and the effectiveness of the prescribed check?

Carry Forward

Document manufacturing commonality, lot history, defect frequency, and detection capability when determining field-action scope. Where continued use depends on a pre-use check, assess whether that check reliably detects the relevant defect under actual use conditions.

7. FDA Revises HBV Testing Recommendations for Blood Donations

FDA's November 3 final guidance, *Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus*, recommends that hepatitis B surface antigen testing is unnecessary for donations other than Source Plasma when they undergo HBV nucleic-acid testing and anti-HBc screening using appropriately authorized tests according to manufacturers' instructions. FDA continues to recommend both HBsAg and HBV NAT testing for Source Plasma.

Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus: Guidance for Industry

The guidance identifies annual reporting as the route for licensed establishments implementing changes consistent with its recommendations, including discontinuation of HBsAg testing and related procedural changes. It treats alternative testing strategies or procedures outside those recommendations as major changes requiring a prior-approval supplement. Establishments that retain their existing testing approach must continue to follow applicable procedures and requirements for managing results.

Source: Download the FDA Final Guidance

Why It Matters

Removing a test changes more than a laboratory workflow. The implementation assessment should address donor eligibility and requalification, product disposition, labeling, procedures, computer systems, and regulatory reporting.

Carry Forward

Map the decisions and system dependencies that use HBsAg results before implementing a change. Confirm that revised procedures, software logic, labeling, and training work together at the point of implementation.

The Week in Context

The common operational issue is the quality of the evidence supporting a decision. A passing retest needs context. A potency result needs an understood relationship to product performance. A records submission needs traceability. A field check needs demonstrated detection capability.

For quality leaders, the useful review question is: **What does this result establish, what remains uncertain, and what evidence supports the decision to proceed?**

That question applies equally to batch disposition, investigation closure, CAPA effectiveness, and changes to an established control strategy.

Worth Reading

1. **Pritam International Warning Letter** — Data integrity, microbiological sample custody, retrospective assessment, and quality-unit oversight.
2. **Next Medical Products Warning Letter** — Retesting, environmental monitoring, CAPA escalation, design changes, and remediation under QMSR.
3. **Potency Assurance for Cellular and Gene Therapy Products** — FDA's final recommendations for integrating potency assurance across the product lifecycle.
4. **Platelet-Sepsis Safety Communication** — Residual risk, evidence preservation, and investigation of each event on its own facts.
5. **HBV Testing Final Guidance** — Revised testing recommendations and associated implementation and reporting considerations.
6. **B. Braun Streamline Alert** and **ButterflyBVM Alert** — Assembly-step control, defect detection, and field-action scope.
7. **Guangdong Bangze**, **Guangzhou Jiugong**, and **Guangdong Bisutang** — Different consequences of inadequate, inconsistent, or unavailable records.

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